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14. ABSTRACT Training specific surgical skills on simulators has been proven to bring a better-prepared student to a human operating room, and when the simulator-trained student performs a portion of a procedure fewer errors are made when compared to a learner who has not been trained on a simulator. This current study seeks to further this work by first developing a curriculum for training an entire procedure, laparoscopic cholecystectomy, using simulation technologies and integrating cognitive, psychomotor aspects of full procedure training, and second, to test the effectiveness of curriculum-based training through a multicenter, international research group, the MASTER group.					
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Introduction

Training specific surgical skills on simulators has been proven to bring a better-prepared student to human operating room, and when the simulator-trained student performs a portion of a procedure fewer errors are made when compared to a learner who has not been trained on a simulator. This current study seeks to further this work by first developing a curriculum for training an entire procedure, laparoscopic cholecystectomy, using simulation technologies and integrating cognitive, psychomotor aspects of full procedure training, and second, to test the effectiveness of curriculum-based training through a multicenter, international research group, the MASTER group.

Body

Thus far the laparoscopic cholecystectomy curriculum including the cognitive and psychomotor components has been developed and validated locally (See Appendix A). Expert performance levels have been established through three separate surveys of advanced laparoscopic surgeons. The first survey was conducted during the 2003 Annual Meeting of the Society of Laparoscopic Surgeons (SLS) where 100 surgeons who had performed in excess of 100 advanced laparoscopic procedures were tested on the MIST-VR. The second occurred during the 2003 Clinical Congress and used the same methodology, and the third during the 2004 Annual SAGES meeting. Results from these surveys have been published and these data are now part of a database for use in setting benchmarks for performance on the MIST-VR (Appendix B & C).

The methodology for executing the study at multiple sites has been developed and distributed (Appendix D). This “cookbook” serves as a step-by-step guide for setting the MIST-VR and establishing local expert levels for collaborating institutions.

Local IRB and DOD HSRRB approval has been acquired at the lead center and other sites are in the process of submitting their local IRBs.

Results from the lead center have shown overall reduction in both time and errors with curriculum-trained group.

Several problems have slowed progress with this project:

1. Technical challenges have become apparent during this time and issues with the durability of simulators has emerged. The MIST is not well supported by industry and there is a need to change the simulation platform to a better and more durable simulator.
2. Programmatic challenges have also hindered this project. Time required to complete a DOD HSRRB application and to receive approval from same far exceeded original expectations. Institutional IRB approval has been problematic due to confusion regarding education research. In most cases, education research is exempt from full IRB review. In this project, the research subjects are students, not patients. When the student is in the operating room and their performance is being videotaped, the attending surgeon is always present and supervises the student at all times. If the student's performance of the operation falls below what would be acceptable for the patient, the attending surgeon takes over the conduct of the operation. This is the standard of care today in all centers with surgical trainees. This take over by the attending is actually a data point which is recorded when the videotaped procedure is scored by blinded reviewers. IRB committees have found this methodology confusing thinking that patients were being exposed to untrained surgeons without oversight. Considerable time was required to educate IRBs on this experimental design.
3. Turnover with collaborating surgeons moving from one academic center to another has meant that some of the original collaborating centers no longer have the skill and leadership to participate in this research. This meant that new centers had to be recruited.

Key Research Accomplishments

1. Designed curriculum including cognitive and psychomotor components
2. Validated curriculum and presented results at national meeting
3. Established expert performance levels and published / presented results
4. Secured IRB and HSRRB approval at lead center
5. Distributed execution methodology to collaborating sites
6. ACS presentation on preliminary, single site results
7. Methodology being used by ABS and others in curriculum design
8. Results from lead center

Reportable Outcomes

Manuscripts

1. Gallagher, A. G., C. D. Smith, et al. (2003). "Psychomotor skills assessment in practicing surgeons experienced in performing advanced laparoscopic procedures." Journal of the American College of Surgeons 197(3): 479-88.
2. Gallagher, A. G., A. B. Lederman, et al. (2004). "Discriminative validity of the Minimally Invasive Surgical Trainer in Virtual Reality (MIST-VR) using criteria levels based on expert performance." Surgical Endoscopy 18(4): 660-5.

Abstracts

1. McClusky, D. M., C. D. Smith, et al. (2004). Virtual Reality Training Improves Operating Room Performance of PGY 1 & 2 Surgical Residents: Results of a Prospective, Randomized, Double-Blinded Study of the Complete Laparoscopic Cholecystectomy. Proceedings of the Surgical Forum, 2004.
2. Van Sickle, K. R., C. D. Smith, et al. (2005). Setting National Benchmark Proficiency Levels for Laparoscopic Performance Using Simulation: The Results from the 2004 SAGES MIST-VR Learning Center Study. SAGES 2005 Annual Meeting, Accepted for Oral Presentation.

Presentations

1. Virtual Reality Training Improves Operating Room Performance of PGY 1 & 2 Surgical Residents: Results of a Prospective, Randomized, Double-Blinded Study of the Complete Laparoscopic Cholecystectomy. American College of Surgeons Surgical Forum, New Orleans, LA, October 13, 2004.

Conclusions

The full procedure curriculum has been developed and validated. Lead center local IRB approval has been secured. New collaborating centers are being recruited. It is anticipated that the 24 study subjects will be enrolled and studies completed in the next 6-9 months. Completion of this work will have significant impact in several ways:

1. This will be the first study to validate the benefit and role of simulation for full procedure training,
2. With the focus on curriculum, and not just a specific surgical skill, this work will catalyze simulation developers to progress past developing technologies that simply train a psychomotor skill, but rather, offerings that incorporate cognitive and psychomotor skills within a curriculum that when integrated into the simulators will provide a package more appealing to the surgical and procedural educators.
3. With the significant logistic issues of conducting multicenter educational research resolved through this project, this methodology can be easily reproduced thereby providing a readily available mechanism to generate significant numbers of subjects in short periods of time to further validate simulation strategies for industry and educators alike.

References

1. Gallagher, A. G., C. D. Smith, et al. (2003). "Psychomotor skills assessment in practicing surgeons experienced in performing advanced laparoscopic procedures." Journal of the American College of Surgeons 197(3): 479-88.
2. Gallagher, A. G., A. B. Lederman, et al. (2004). "Discriminative validity of the Minimally Invasive Surgical Trainer in Virtual Reality (MIST-VR) using criteria levels based on expert performance." Surgical Endoscopy 18(4): 660-5.

APPENDIX A

Presented at 2004 ACS Surgical Forum

Virtual Reality Training Improves Operating Room Performance of PGY 1 & 2 Surgical Residents: Results of a Prospective, Randomized, Double-Blinded Study of the Complete Laparoscopic Cholecystectomy.

Objective

To demonstrate that virtual reality (VR) training improves technical skills of junior residents in the operating room during completion of the full laparoscopic cholecystectomy (LC).

Summary Background Data

VR training has been demonstrated to improve technical skills of PGY 1-4 residents during the final dissection portion of a LC.

Methods

Eleven surgical residents (PGY 1 & 2) had baseline psychomotor, visio-spatial and perceptual abilities assessed and were then randomized to either Control (n=6) or VR training with MIST VR simulator (n=5) until performance criterion levels established by experienced laparoscopists were achieved. All subjects performed a video-recorded LC with a supervising attending surgeon blinded to training status. Video-recordings were assessed by two surgeon investigators blinded to subject identity and training status and scored using pre-defined errors for exposure (n = 11), clipping and dissection (n = 12), and dissection of the gallbladder from the liver-bed (n = 8) with inter-rater reliability (IRR) >0.8 (mean IRR = 0.96).

Results

VR trained subjects completed the full LC 20% faster than controls (31.2 v. 39.2 minutes) and made half as many errors during exposure of the cystic duct structures (5.4 v. 10, $p < 0.04$) and dissection of the gallbladder off the liver-bed (4 v. 7.2, $p < 0.03$). Overall, controls made twice as many intra-operative errors (10 v. 5.4, $p < 0.04$) with four times the variability of VR trained subjects.

Conclusion

Criterion based VR training for junior surgical residents transfers to reduced intra-operative errors and greater performance consistency for the entire LC.

Psychomotor Skills Assessment in Practicing Surgeons Experienced in Performing Advanced Laparoscopic Procedures

Anthony G Gallagher, PhD, C Daniel Smith, MD, FACS, Steven P Bowers, MD, Neal E Seymour, MD, FACS, Adam Pearson, BSc, Steven McNatt, MD, David Hananel, BSc, Richard M Satava, MD, FACS

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- BACKGROUND:** Minimally invasive surgery (MIS) has introduced a new and unique set of psychomotor skills for a surgeon to acquire and master. Although assessment technologies have been proposed, precise and objective psychomotor skills assessment of surgeons performing laparoscopic procedures has not been detailed.
- STUDY DESIGN:** Two hundred ten surgeons attending the 2001 annual meeting of the American College of Surgeons in New Orleans who reported having completed more than 50 laparoscopic procedures participated. Subjects were required to complete one box-trainer laparoscopic cutting task and a similar virtual reality task. These tasks were specifically designed to test only psychomotor and not cognitive skills. Both tasks were completed twice. Performance of tasks was assessed and analyzed. Demographic and laparoscopic experience data were also collected.
- RESULTS:** Complete data were available on 195 surgeons. In this group, surgeons performed the box-trainer task better with their dominant hand ($p < 0.0001$) and there was a strong and statistically significant correlation between trials ($r = 0.47 - 0.64$, $p < 0.0001$). After transforming raw data to z-scores (mean = 0 and SD = 1) it was shown that between 2% and 12% of surgeons performed more than two standard deviations from the mean. Some surgeons' performance was 20 standard deviations from the mean. Minimally Invasive Surgical Trainer Virtual Reality metrics demonstrated high measurement consistency as assessed by coefficient alpha ($\alpha = 0.849$).
- CONCLUSIONS:** Objective assessment of laparoscopic psychomotor skills is now possible. Surgeons who had performed more than 50 laparoscopic procedures showed considerable variability in their performance on a simple laparoscopic and virtual reality task. Approximately 10% of surgeons tested performed the task significantly worse than the group's average performance. Studies such as this may form the methodology for establishing criteria levels and performance objectives in objective assessment of the technical skills component of determining surgical competence. (J Am Coll Surg 2003;197:479-488. © 2003 by the American College of Surgeons)
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The introduction of laparoscopic or minimally invasive surgery (MIS) changed the way patients wanted their

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surgery performed and the way surgeons thought about doing surgery. Although MIS conferred considerable advantages on the patient, it imposed major disadvantages on the surgeon; MIS is more demanding, requiring greater concentration than open surgery. Operating times are longer, with increased surgical fatigue and stress from the remote interface required with the laparoscopic approach.¹ The surgeon must reconstruct a three-dimensional mental image of internal organs and structure from a two-dimensional image provided by the charged-couple device (CCD) camera and monitor. Although the images captured by the CCD device and displayed on the monitor are of very high quality, the images they produce are orders of magnitude poorer

Abbreviations and Acronyms

CI	= correct incision
ICI	= incorrect incision
MIS	= minimally invasive surgery
MIST VR	= Minimally Invasive Surgical Trainer Virtual Reality
VR	= virtual reality

than would be produced by the eye under natural viewing conditions.² The surgeon also has to cope with the reduced degrees of freedom of the surgical instruments in comparison to open surgery. This makes tasks that are relatively straightforward in open surgery (eg, suturing) very difficult with the minimally invasive approach. Finally, the surgeon has to overcome or "automate" to the counterintuitive movement of instruments because of the fulcrum effect of the body wall on instrument handling.³ This means that when the surgeon moves his hand to the right, the working end of the instrument within view on the monitor moves to the left and vice versa. The fulcrum effect causes a fundamental visual-proprioceptive conflict that can only be overcome with extended practice.⁴ These problems mean that minimally invasive surgeons must operate at the very edge of their perceptual, cognitive, and psychomotor abilities.

When minimally invasive surgery was first introduced, a number of studies reported higher complications than open approaches, particularly during the early part of the minimally invasive surgeon's career.^{5,6} Other studies have reported that complications persist even with very experienced surgeons.^{7,8} The precise reasons for the complications experienced by senior surgeons are unclear.⁹ It could be that very experienced surgeons are referred more difficult cases, or there is a MIS skills deficit.

Surgeons in training, by their very definition, have a skills deficit, but these are often overcome with training in 1- to 3-day MIS courses, increasing operative exposure, and mentoring. But surgeons in training acquire these skills at different rates, and, indeed, some may not ever acquire a sufficient level of skill to perform safe MIS. Cuschieri¹ has estimated that between 5% and 10% fall into this group. One of the major problems in attempting to establish whether a surgeon in training has acquired the psychomotor skills to perform MIS is the current absence of benchmarks. Rosser and colleagues¹⁰ have used intracorporeal suturing as an indicator of skill

level. A problem with the results of this assessment of intracorporeal knot tying is that time was the only benchmark metric. The inadequacy with this metric is that although a surgeon could tie a knot quickly, this gives no indication of the quality of the knot.

An alternative approach would be to use virtual reality (VR) tasks to assess performance. The advantage of this approach is that precise metrics can be extracted from MIS performance on these computer-generated and tracked tasks. A number of researchers have taken this approach. Several studies have shown that a VR trainer (the Minimally Invasive Surgical Trainer or MIST VR, Mentice AB) was sensitive enough to distinguish between surgeons of different levels of experience in the psychomotor skills of: speed of performance (completion time), errors made, economy of instrument usage (path length), and economy of diathermy.¹¹⁻¹³ As manifested by the designed tasks listed above, the MIST VR simulator is designed to test only perceptual abilities and psychomotor skills; there is no component of cognitive skills or decision making in the simulation. In a later study, Gallagher and Satava¹⁴ investigated these designed psychometric properties of MIST VR. They found that the simulator had a high test-retest reliability and a high alpha coefficient (ie, a measure of internal measurement consistency), and distinguished between surgeons in terms of learning curves and variability of performance (construct validity). All of these studies concluded that MIST VR could be a useful device for assessing MIS performance in the laboratory, particularly because of its performance metrics for psychomotor skills.

Following the above validation (face, concurrent, construct, and content validity) of the MIST VR as a system to train and assess psychomotor skills, the simulator was evaluated for predictive validity: Is the system a valid predictor of the performance of psychomotor (not cognitive) skills in the operating room? Seymour and colleagues¹⁵ demonstrated that residents trained on the MIST VR simulator (as compared with a control group with no simulator training) made fewer errors and used less time for the gallbladder excision portion of a laparoscopic cholecystectomy on patients.

But a major obstacle to implementing MIST VR as an assessment device is that the studies that have been conducted have used only small numbers of participants. It is also not clear how an individual's performance on a VR task relates to performance of an entire surgical procedure on a real-world task. More important, there is no

study to date (and it may take decades) to prove that training on a simulator directly improves outcomes (patient safety, decreased complications, higher quality of life).

The purpose of the study reported here was to benchmark MIS performance of psychomotor skills of experienced minimally invasive surgeons on a VR task and a similar box-trainer task. The box-trainer task, a simple laparoscopic paper-cutting task, was chosen because it was first used to empirically demonstrate the impact of the fulcrum effect on MIS performance and has subsequently been used extensively to assess different MIS training programs.^{3,16-19} It has also been demonstrated to have low variability, normally distributed performance, and is sensitive to learning and errors. This relatively simple laparoscopic task also requires little cognitive effort (ie, remembering what to do), so is a good measure of laparoscopic psychomotor performance. For the purposes of this study a similar VR task was constructed. It was predicted that experienced minimally invasive surgeons would demonstrate variability in their performance on both a virtual reality task and a box-trainer task, although the majority of surgeons' performance would fall within a range plus or minus two standard deviations from the mean. Another prediction was that performance on the box-trainer and VR task would correlate strongly enough to allow only the VR task to be used in future studies.

METHODS

Subjects

Surgeons attending the 2001 annual meeting of the American College of Surgeons in New Orleans participated. Two hundred ten surgeons were recruited, and 15 surgeons failed to complete any single task. Their data were excluded from subsequent analysis. Demographic details of surgeons who participated are shown in Table 1.

Apparatus

MIST VR

The MIST VR system comprises a standard 200-MHz PC with 32 Mb RAM, linked to a jig containing two laparoscopic instruments held in position-sensing gimbals with 5 degrees of freedom. This provides real-time translation of the instrument movements to the graphic display on a 15-inch color monitor. An accurately scaled operating volume of 10 cm³ is represented

Table 1. Demographic Details of Surgeons Tested.

Age (y)	
30-39	24.6%
40-49	40%
50-59	23%
60-69	12.4%
>70	0%
Mean number of career laparoscopic cases	967 (SD = 994; range 20-4,000)
Mean number of laparoscopic cases per year	144 (SD = 105; range 2-400)
Right hand dominant	92.3%
Male	86%

by a three-dimensional cube on the computer screen. The image zoom and size of the target objects can be varied. Circular targets (at a diameter of 12 mm) appear randomly within the operating volume and can be "grasped" and "manipulated." The MIST VR trainer recorded time, error, and economy of instrument movement relative to the target object. A novel MIST VR task was developed for this study and is shown in Figure 1. It consisted of a rectangular virtual card with five spheres along the long edge and a larger sphere in the middle of the short edge. The large sphere indicated which hand or instrument was to be used to grasp the card and where subjects should start excising the spheres. The hand or instrument used to grasp the card alternated with each card completed.

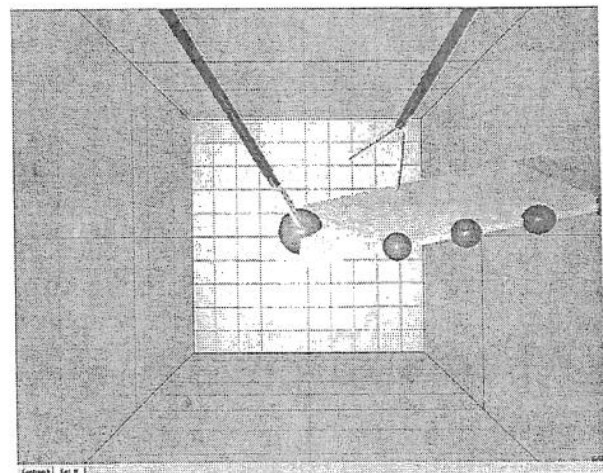


Figure 1. The new MIST VR task for the 2001 American College of Surgeons objective assessment of laparoscopic psychomotor skill program. MIST VR, Minimally Invasive Surgical Trainer Virtual Reality.

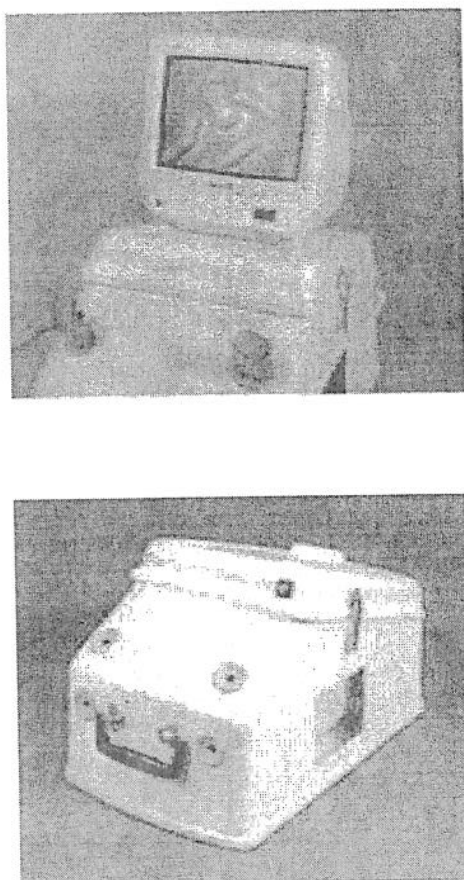


Figure 2. The portable laparoscopic box trainer.

Box-trainer task

A standard laparoscopic cutting task was used as previously reported.^{3,16} Briefly, a cut is made in 26 spaces clearly demarcated by black lines along the long edge of a sheet of paper. The task was performed in a Portable Laparoscopic Trainer (3-D Technical Services, Franklin, OH) (Fig. 2). Ethicon nontoothed laparoscopic forceps (Ethicon Endosurgery, Cincinnati, OH) and laparoscopic curved scissors were used to hold and cut the paper. This task has been shown to be sensitive to differences between experienced and junior surgeons, is sensitive to learning, measures correct responses and errors, has low variability, and has been demonstrated to conform to the Gaussian distribution.

Procedure

Subjects reported to the testing booth in the scientific exhibition area of the conference and completed a questionnaire detailing their experience and training. After confirming that they had completed more than 50 lapa-

roscopic procedures, they were given a unique identifier number and then watched a video recording explaining how to perform the laparoscopic tasks, including what constituted an error. Subjects rotated through four testing stations in alternate order, two virtual reality stations and two box-trainer cutting stations. The virtual reality task required subjects to hold the virtual card with one instrument and excise the spheres by grasping them in the center with the other instrument. When this was done correctly the sphere disappeared. The virtual reality task always started with the subjects holding the sphere with their nondominant hand and excising the spheres with their dominant hand. After all five spheres had been excised, a new card appeared and was to be grasped with the dominant hand. All subjects were required to complete four cards with a total of 20 spheres. Timing was stopped between all the spheres being excised for one card and a new card appearing. MIST VR recorded time, errors, and economy of instrument movement.

The laparoscopic cutting task was placed horizontally in a conventional box trainer under standardized laparoscopic conditions. Subjects were required to make one incision between 26 spaces clearly demarcated by black lines along the long edge of the sheet of paper (US letter). Subjects grasped the paper with their nondominant hand and cut with their dominant hand for the first trial and then swapped over for the second trial. An error was judged to have been made if a subject's incision cut across one of the black lines or touched it. If an incision was so close to the line that the experimenter found it difficult to make a decision it was judged an error. Twenty percent of sheets were rechecked by another investigator. The inter-rater reliability was 98%. Subjects were asked to make as many incisions as they could in two 2-minute periods. The laparoscopic task was removed from the box trainer after each subject was finished. Timing commenced when subjects placed the paper between the jaws of the scissors for their first incision. Subjects were stopped after 60 seconds had elapsed.

RESULTS

The means and standard deviations of surgeon performance on the box trainer and VR tasks are shown in Table 2. Differences between performance on the two trials were compared for significance with ANOVA for repeated measures and these results are shown in Table 3.

Results for the box-trainer task reveal that surgeons

Table 2. Mean Scores by Surgeons on the Box Trainer and Virtual Reality Tasks for Trials 1 and 2 and Their Intercorrelation

	Trial 1 mean (SD)	Trial 2 mean (SD)	<i>r</i>	<i>df</i>	<i>F</i> value	<i>p</i> Value
Box trainer metrics						
Correct incisions	19.1 (5.4)	17.7 (6)	0.644	1,191	135.1	0.0001
Incorrect incisions	3.03 (7.3)	5.14 (13)	0.472	1,191	54.6	0.0001
MIST VR metrics						
Time	98.9 (54.3)	76.51 (43)	0.487	1,183	56.3	0.0001
Errors	64.3 (54.4)	53 (38.5)	0.48	1,181	9.59	0.0023
Economy of movement	15.7 (8.5)	12.75 (6.2)	0.553	1,182	79.7	0.0001

MIST VR, Minimally Invasive Surgical Trainer Virtual Reality.

made significantly more correct incisions (CI) with their dominant hand in trial 1 than they did with their non-dominant hand during trial 2. They also made significantly more incorrect incisions (ICI) during trial 2. The percentage of ICI scores showed considerable variability, with standard deviations that were twice as large as the mean scores for both trials.

Performance as a function of hand dominance was not assessed separately for MIST VR because the tasks alternated which hand did most of the work. Across all three measures there was a statistically significant improvement between trials 1 and 2. There was considerable variability in all of the VR scores on trial 1 but this had decreased by trial 2. Pearson's Product Moment Correlation Coefficient was used to assess how strongly performance on the first trial was related to performance on the second trial. These are presented in Table 1 with *F* values and probability levels. Performance on trial 1 was strongly and statistically significantly related to performance on trial 2 across both the box trainer and MIST VR measures, with correlations ranging from *r* = 0.48 to 0.644.

For ease of analysis all scores for each measure were transformed to z-scores using the mean and standard deviation of each measure for each trial. The advantage of this approach is that the mean = 0 with a standard deviation = 1. Any scores falling more than two standard deviations either way from the mean differ statistically significantly at the 95% probability level from the sample mean. Figure 3A shows the distribution of CI z-scores for trials 1 and 2 (dominant hand on trial 1 and nondominant hand on trial 2). From the graph it can be seen that some individuals are scoring four standard deviations from the mean, indicating that they are making dramatically fewer CI than the mean performance: 2.1% in trial 1 and 2.6% of subjects in trial 2. A statistical problem created by these outliers is that they were

used in the calculation of the z-scores, so will likely negatively bias the distribution. To eliminate this problem, new means and standard deviations were calculated for each of the metrics and for each trial based only on the scores of surgeons who fell within plus or minus two standard deviations. These are presented in Table 4.

All subsequent graphs show the raw z-scores on the upper plate (A) and the biweighted z-scores on the lower plate (B). Even with the biweighted transformation shown in Figure 3B, 4.1% of surgeons scored more than two standard deviations away from the mean.

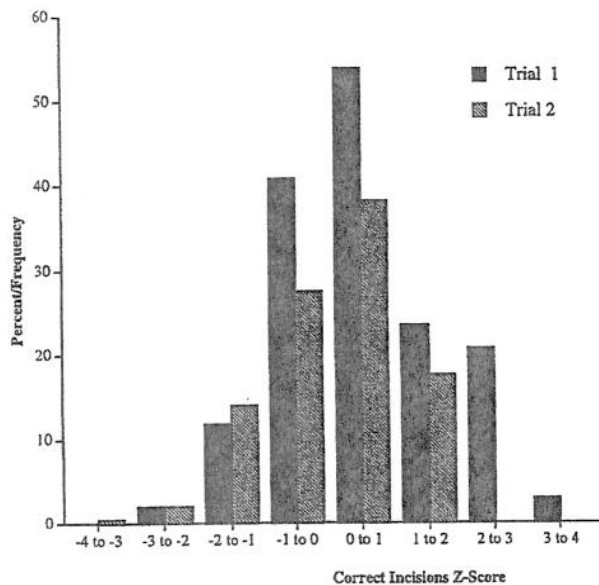
Figures 4A and 4B show the distribution of scores for ICIs. Most surgeons' performance bunched around the mean, but both distributions exhibit a long tail. For the raw z-scores, 5.64% of surgeons scored more than two standard deviations away from the mean, but for the biweighted mean this was 12.3%. Indeed, for the biweighted distribution some surgeons scored more than 13 standard deviations from the mean on trial 1 and up to 20 on trial 2.

Although the MIST VR time scores show a more even distribution (Figs. 5A and 5B) than the ICI scores, they also exhibit a long tail. For the raw z-scores, 6.3% and 7% of surgeons scored more than two standard devia-

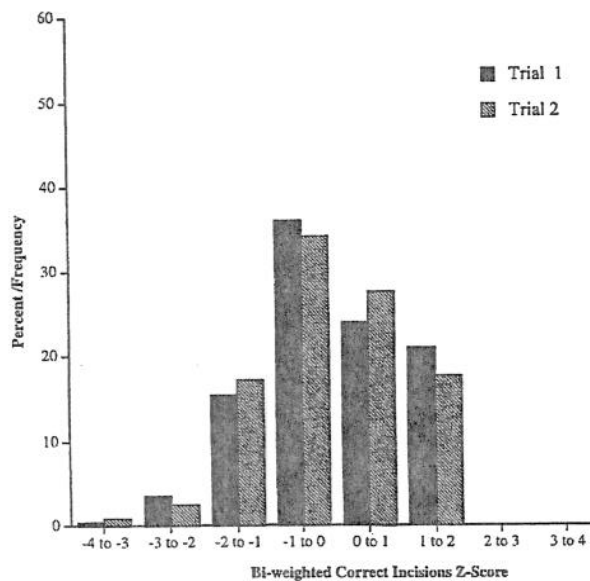
Table 3. Results of ANOVA for Repeated Measure Between the Difference in Performance on Trial 1 and Trial 2

	<i>df</i>	<i>F</i> value	<i>p</i> Value
Box trainer metrics			
Correct incisions	1,191	16.45	0.0001
Incorrect incisions	1,191	54.6	0.0001
MIST VR metrics			
Time	1,183	36.52	0.0001
Errors	1,181	54.3	0.0023
Economy of movement	1,182	30.76	0.0001

MIST VR, Minimally Invasive Surgical Trainer Virtual Reality.



A



B

Figure 3. (A and B) Distribution of z-scores for correct incisions made during the two 2-minute trials.

tions from the mean for trials 1 and 2, respectively. The biweighted z-distribution exhibited 11.6% and 8.6%. No surgeon performed more than five standard deviations from the mean.

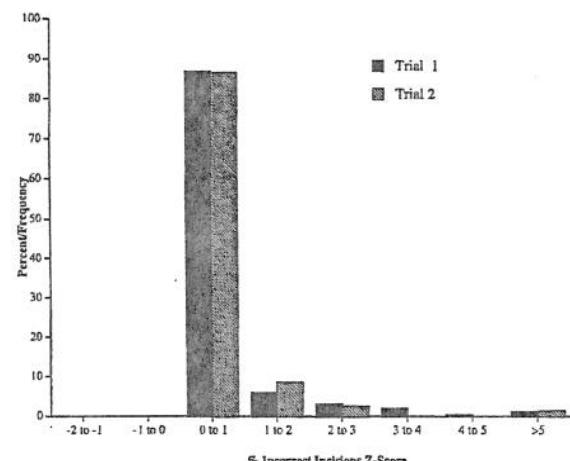
MIST VR error scores are presented in Figures 6A and 6B. Most surgeon performance bunches around the mean, but both distributions exhibit a long tail. In trials 1 and 2, 5.8% and 5.4% scored more than two standard

Table 4. Biweighted Mean Scores by Surgeons on the Box Trainer and Virtual Reality Tasks for Trials 1 and 2

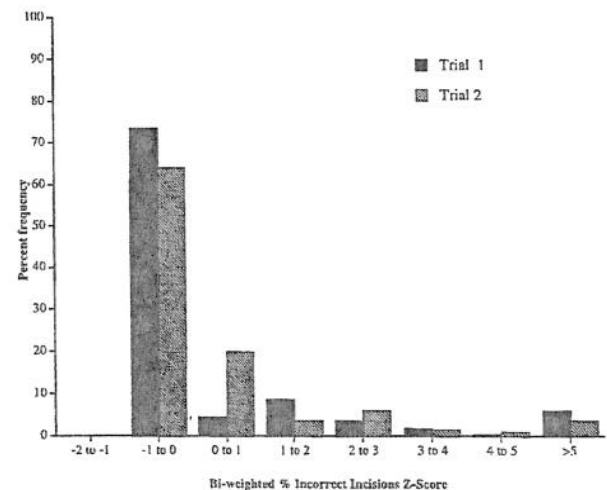
	Trial 1 mean (SD)	Trial 2 mean (SD)
Box trainer metrics		
Correct incisions	19.4 (5.03)	18.05 (5.89)
Incorrect incisions	1.37 (2.95)	3.02 (5.28)
MIST VR metrics		
Time	89.7 (39.49)	68.22 (27.28)
Errors	55.23 (38.5)	47.72 (28.61)
Economy of movement	14.38 (6.12)	11.78 (4.3)

MIST VR, Minimally Invasive Surgical Trainer Virtual Reality.

deviations away from the mean for the raw z-scores, respectively. This increased to 10% and 10.7% for the biweighted distribution. Indeed, some surgeon perfor-

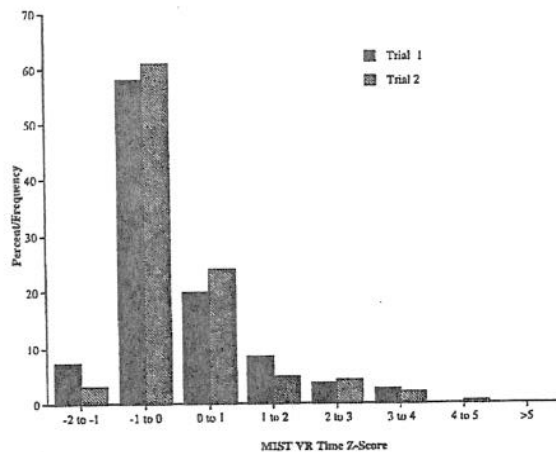


A

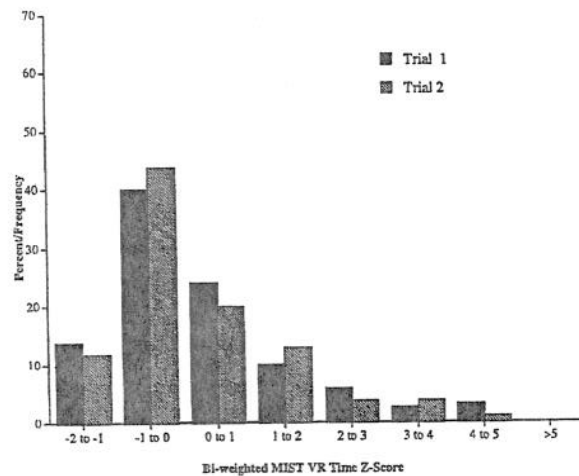


B

Figure 4. (A and B) Distribution of z-scores for incorrect incisions made during the two 2-minute trials.



A

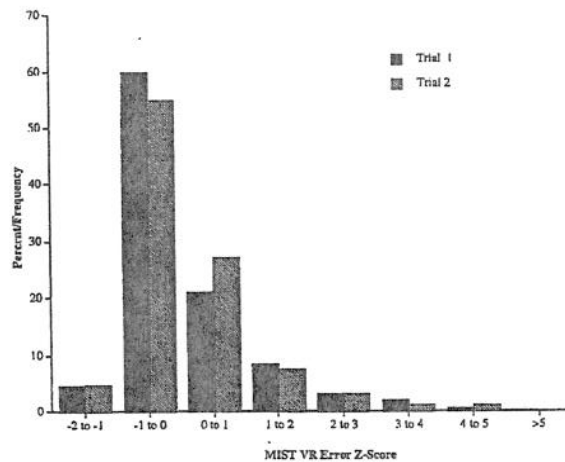


B

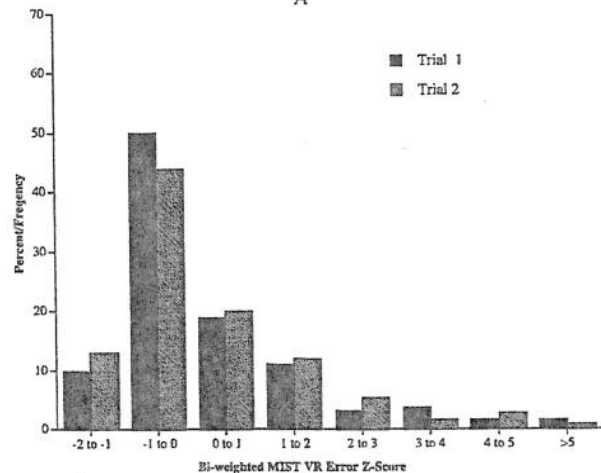
Figure 5. (A and B) Distribution of z-scores for time performance metric on MIST VR for trials 1 and 2. MIST VR, Minimally Invasive Surgical Trainer Virtual Reality.

mance fell seven standard deviations from the mean for both trials 1 and 2.

Economy of instrument movement exhibited a similar pattern to the error scores. Figures 7A and 7B show that most of the scores bunch around the mean, and, similar to the other scores, exhibit a long tail. The top plate (Fig. 7A) shows that 5.8% and 5.3% of surgeons in trials 1 and 2 performed more than two standard deviations from the mean. For the biweighted distribution it was 11.5% and 9.6%, respectively. One surgeon performed eight standard deviations from the mean. Coefficient alpha was used to assess the internal measurement consistency of the MIST VR metrics and was observed to be high; $\alpha = 0.849$.



A



B

Figure 6. (A and B) Distribution of z-scores for error performance metric on MIST VR for trials 1 and 2. MIST VR, Minimally Invasive Surgical Trainer Virtual Reality.

DISCUSSION

Most studies on the objective assessment of laparoscopic performance have only used small numbers of subjects (eg, 9, 10, 11, 12) and when larger numbers have been used only crude measures (eg, time) have been reported. This is one of the first studies to use both a box-trainer task and a virtual reality task. We also tested only experienced laparoscopic surgeons, ie, surgeons who claimed to have performed more than 50 laparoscopic operations. Surgeons performed better with their dominant hand in trial 1 of the box-trainer cutting task. On the MIST VR tasks there was a significant improvement between trials 1 and 2.

One goal of this study was to objectively assess whether some surgeons were performing worse than the

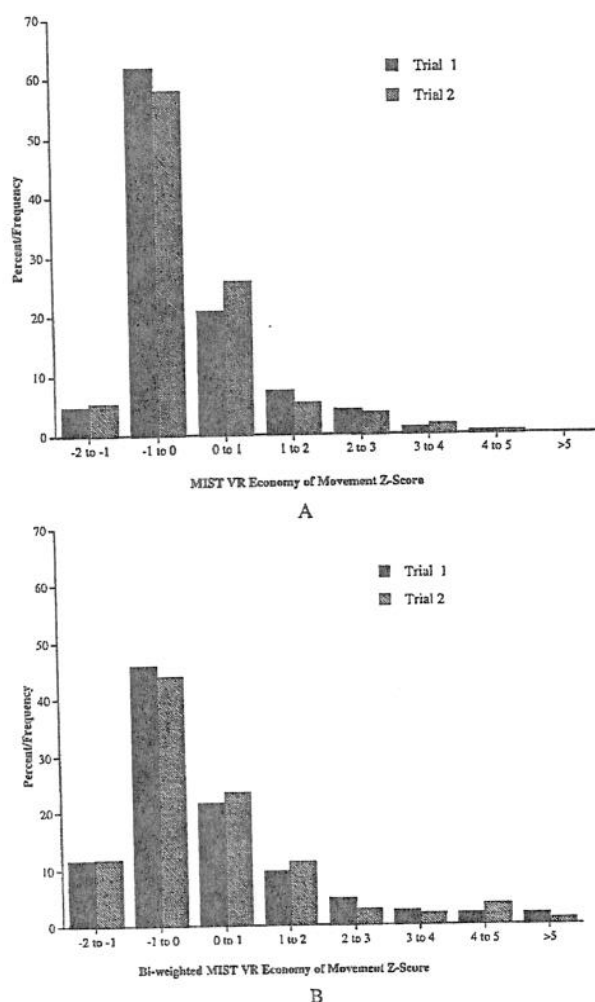


Figure 7. (A and B) Distribution of z-scores for economy of movement performance metric on MIST VR for trials 1 and 2. MIST VR, Minimally Invasive Surgical Trainer Virtual Reality.

mean and, if so, how much worse. The box-trainer and VR task were chosen because they were extremely simple and involved little cognition or decision making, so they should have given a pure measure of psychometric performance. Indeed, before the data collection started, some of the coauthors expressed concern that the tasks were too simple and would not be challenging enough for experienced laparoscopic surgeons. After data collection started it was evident that even such a simple basic skill was a sensitive discriminator. Some surgeons excelled at both tasks, but others had great difficulty performing either the VR or the box-trainer task. The results we have presented here are from only surgeons who completed some part of the study. Fifteen surgeons had

to be excluded because they did not complete any part of the study.

One of the findings that surprised all the authors was how poorly some surgeons performed (eg, up to 20 standard deviations from the mean). Reassuringly, this number was extremely small. But what this study has demonstrated is that based on objective metrics it is possible to identify individuals who have laparoscopic basic psychomotor skill deficits. Both the box-trainer task and the VR task achieved this and corroborate the veracity of the results. But the VR task generates the metrics automatically, and records performance and provides more comprehensive performance metrics in comparison to the box-trainer task, in which the experimenter has to physically count the number of incisions. Although the inter-rater reliability observed in this study was very high, there is always the possibility of human error with the box trainer. The box-trainer task that was used was simple, with only two possible outcomes, both of which were clearly defined. Had a more complicated task been used, the inter-rater reliability may not have been as high. MIST VR has also been the subject of extensive validation studies⁹⁻¹² and is currently the best validated VR system in surgical education. These MIST VR validation studies used the original six tasks that were developed to teach psychomotor skills and instrument handling for laparoscopic cholecystectomy. The study reported here used a novel task to eliminate the effect of earlier exposure. No surgeon had worked on the new VR task before the American College of Surgeons 2001 meeting. One advantage that the box-trainer task had over the VR task was that dominant and nondominant hand performance were assessed separately. In a new study we plan to assess dominant hand performance on both the box trainer and virtual environments and how strongly performance on one correlates with the other.

Currently, surgical residents wishing to pursue a career in minimally invasive surgery have no objective national or international benchmarks at which to aim. They can only use local attending surgeon performance, and frequently the local training institution has not validated a criterion level to achieve, so training is focused on training time, rather than objective criteria for proficiency. What the data from this study have shown is that there is considerable variability in surgeon performance, which we assume translates nationally. We believe that this issue will become more important. In the recent study by Seymour and Colleagues,¹⁵ the benefits of

benchmarking were clear. In a prospective, randomized, double-blind trial of VR training versus standard surgical training, the researchers found that surgical residents trained on VR simulators made significantly fewer errors during a laparoscopic cholecystectomy. One of the crucial aspects of this study was that the residents were trained to an objectively measured score (as determined by assessment of attending surgeon psychomotor performance levels on the VR simulator), and were required to reach this established performance level (criteria) on two consecutive trials before being allowed to operate on a patient.¹⁵ The results of that study suggested that surgical residents clearly demonstrated their ability to achieve a criterion level, but some took longer than others. Surgical residents should be given clear guidance as to the standard of psychomotor performance they should achieve (benchmark) before operating on a patient.

Study limitations

One of the limitations of this study is that the "experts" volunteered, so they self-defined "laparoscopic surgeon." We have no objective independent information on what types of MIS they performed other than their self-reports, and we have no information on their performance in the operating room, ie, outcomes data. Another limitation of this study was that the tasks were probably too easy for the expert laparoscopic surgeon. This was most clearly demonstrated on the box-trainer task, where some surgeons made incisions in all 26 spaces, with no errors, in less than a minute. Other factors that might have affected performance relate to the fact that it was in a busy booth in the convention exhibit hall; there were distractions from the convention or they may have been tired after a long flight or busy meeting schedule. Last, because of time constraints, demographic information was self-reported rather than objectively assessed; eg, handedness.

In conclusion, this study has shown that using already validated methods of laparoscopic skills assessment, it is possible to measure laparoscopic psychomotor performance of laparoscopic surgeons who had performed more than 50 laparoscopic procedures by using a simple box-trainer task and a virtual reality task. Between 2% and 12% of surgeons assessed fell more than two standard deviations away from the mean. The majority of surgeons fell within the two standard deviations but considerable variability in performance was observed. Some surgeons' scores fell 20 standard deviations from the

mean. This type of performance is unlikely to have occurred by chance because a large and statistically significant correlation was observed between trials.

Author contributions

Study conception and design: Gallagher, Smith, Bowers, Seymour, Pearson, McNatt, Hananel, Satava
Acquisition of data: Gallagher, Smith, Bowers, Seymour, Pearson, McNatt, Hananel
Drafting of manuscript: Gallagher
Critical revision: Gallagher, Smith, Seymour, Satava
Statistical expertise: Gallagher
Obtaining funding: Smith, Hananel, Satava

REFERENCES

1. Cuschieri A. Whither minimal access surgery: Tribulations and expectations. *Am J Surg* 1995;169:9-19.
2. Cuschieri A. Visual displays and visual perception in Minimal Access Surgery. *Sem Lap Surg* 1995;2:209-214.
3. Reinhardt-Rutland, AH, Gallagher AG. Visual depth perception in minimally invasive surgery. In: Robertson SA, ed. *Contemporary ergonomics*. London: Taylor & Francis; 1996:531-536.
4. Gallagher AG, McClure N, McGuigan J, et al. An ergonomic analysis of the 'Fulcrum Effect' in endoscopic skill acquisition. *Endoscopy* 1998;30:617-620.
5. Crothers I, Gallagher AG, McClure N, et al. Experienced surgeons are automated to the fulcrum effect; an ergonomic demonstration. *Endoscopy* 1999;31:365-369.
6. Wherry DC, Rob CG, Marohn MR, et al. An external audit of laparoscopic cholecystectomy performed in medical treatment facilities of the Department of Defense. *Ann Surg* 1994;220:626-634.
7. The Southern Surgeons Club. The learning curve for laparoscopic cholecystectomy. *Am J Surg* 1995;170:55-59.
8. Gigot J-F, Etienne J, Aerts R, et al. The dramatic reality of biliary tract injury during laparoscopic cholecystectomy; an anonymous multi-center survey of 65 patients. *Surg Endosc* 1997;11:1171-1178.
9. Archer SB, Brown DB, Smith CD, et al. Bile duct injury during laparoscopic cholecystectomy: Results of a national survey. *Ann Surg* 2001;234:549-559.
10. Rosser JC, Rosser LE, Savalgi RS. Objective evaluation of laparoscopic surgical skill program for residents and senior surgeons. *Arch Surg* 1998;133:657-661.
11. Smith CD, Farrell TM, McNatt SS, Metreveli RE. Assessing laparoscopic manipulative skills. *Am J Surg* 2001;181:547-550.
12. Taffinder N, Sutton C, Fishwick RJ, et al. Validation of virtual reality to teach and assess psychomotor skills in laparoscopic surgery: results from randomised controlled studies using the MIST VR laparoscopic trainer. *Stud Health Tech Inform* 1998;50:124-130.
13. McNatt SS, Smith CD. A computer-based laparoscopic skills assessment device differentiated experience from novice laparoscopic surgeons. *Surg Endosc* 2001;15:1085-1089.
14. Gallagher AG, McGuigan J, Ritchie K, et al. Objective psy-

- chomotor assessment of senior, junior and novice laparoscopists with virtual reality. *World J Surg* 2001;25:1478-1483.
15. Seymour N, Gallagher AG, Satava RM, O'Brien, et al. Virtual reality training improves operating room performance: Results of a randomized, double-blinded study. *Ann Surg* 2002;238:458-464.
 16. Gallagher AG, Satava RM. Objective assessment of experience, junior and novice laparoscopic performance with virtual reality: Learning curves and reliability measures. *Surg Endosc* (In press).
 17. Gallagher AG, Hughs C, Reinhardt-Rutland AH, et al. Transfer of skill from 'virtual reality' (VR); a case control comparison of traditional and VR training in laparoscopic skill acquisition. *MITAT* 2000;9:347-352.
 18. Jordan JA, Gallagher AG, McGuigan J, et al. A comparison between randomly alternating imaging, normal laparoscopic imaging and virtual reality training in laparoscopic psychomotor skill acquisition. *Am J Surg* 2000;180:208-211.
 19. Jordan JA, Gallagher AG, McGuigan J, et al. Virtual reality training leads to faster automation of the novel psychomotor restrictions encountered by laparoscopic surgeons. *Surg Endosc* 2001;15:1080-1084.

APPENDIX C

Accepted for Oral Presentation at SAGES 2005 Annual Meeting

Setting National Benchmark Proficiency Levels for Laparoscopic Performance Using Simulation:
The Results from the 2004 SAGES MIST-VR Learning Center Study

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Background: The Minimally Invasive Surgical Trainer Virtual Reality (MIST-VR) (Mentice, Gottenberg, Sweden) has been well validated as a training device for laparoscopic skills. Training to a level of proficiency on the simulator has been demonstrated to significantly improve objectively assessed operating room performance during laparoscopic cholecystectomy. The purpose of this project was to establish a national standard of proficiency on the simulator based on the performance of experienced laparoscopic surgeons. **Methods:** Surgeons attending the SAGES 2004 Annual Meeting who had performed more than 100 laparoscopic procedures volunteered to participate and were tested in the SAGES Learning Center. All subjects completed a demographic questionnaire to assess laparoscopic and/or MIST-VR experience. Each subject performed two consecutive trials of the MIST-VR Core Skills 1 program on medium settings (six basic tasks of increasing difficulty; acquire place (AP), transfer place (TP), traversal (TV), withdrawal insert (WI), diathermy task (DT), manipulate diathermy (MD)). Trial 1 was considered a "warm-up" and Trial 2 functioned as the test trial proper. Subject performance was scored for time, errors and economy of instrument movement for each task, and a cumulative total score was calculated. **Results:** 57 surgeons participated in the study, complete data is available for 42. Trial 2 data expressed as mean \pm SD; time in seconds; other values unitless.

Task	Econ L	Econ R	Errors L	Errors R	Tot. Time	Score
AP	2.6 \pm 0.6	2.4 \pm 0.6	5.0 \pm 4.3	4.1 \pm 3.2	12.5 \pm 2.8	26.7 \pm 9.2
TP	3.0 \pm 1.0	2.8 \pm 0.8	8.8 \pm 7.0	7.8 \pm 6.0	18.4 \pm 5.1	38.4 \pm 14.0
TV	5.3 \pm 2.0	5.1 \pm 1.8	15.7 \pm 14.0	11.2 \pm 10.3	36.6 \pm 14.5	73.8 \pm 34.9
WI	2.0 \pm 0.3	2.0 \pm 0.5	4.7 \pm 4.1	4.4 \pm 5.7	15.3 \pm 4.3	27.3 \pm 11.4
DT	2.7 \pm 0.7	2.4 \pm 0.6	7.7 \pm 5.1	8.2 \pm 5.6	20.5 \pm 4.7	41.6 \pm 11.4
MD	2.4 \pm 0.6	2.3 \pm 0.7	51.9 \pm 35.3	53.3 \pm 34.1	50.9 \pm 26.9	160.7 \pm 92.9
MIST-VR Core Skills 1 Total Score						374.8 \pm 134

Conclusion: National benchmark proficiency levels for laparoscopic skills have now been established by experienced laparoscopic surgeons using the MIST-VR simulator. Residency programs, training centers and practicing surgeons can now use these data to identify how their skills compare to laparoscopic surgeons nationwide, and to set performance goals accordingly.

APPENDIX D

MASTER Curriculum-based training for laparoscopic cholecystectomy multicenter trial

Guide for establishing expert criterion levels for the MIST-VR

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Introduction

The MASTER curriculum based laparoscopic cholecystectomy (CBLC) multicenter trial is designed to assess whether residents trained using a uniquely designed curriculum that includes virtual reality laparoscopic training on the MIST-VR make fewer errors in the performance of laparoscopic cholecystectomy than residents who undergo standard training without such a curriculum. This design requires that residents randomized to the curriculum training arm of the study train on the MIST-VR to a certain performance level (or criterion) prior to performing human laparoscopic cholecystectomy. Currently, this performance level is not set. Consequently, training cannot proceed until these levels are established.

Based on previous models assessing the utility of the MIST-VR as a training modality, this study calls on experts, who have performed at least 100 laparoscopic cholecystectomies, to set the MIST-VR performance criterion that curriculum trained residents will need to achieve. The initial phase of this trial, therefore, is to analyze the MIST-VR performance of experts at participating institutions. This guide is intended to help your institution collect the necessary data so this analysis can occur as soon as possible. Specifically it outlines the steps needed to configure your MIST-VR for trial participation, and describes the process of saving and packaging the data for statistical analysis at Emory.

Before you set up your MIST-VR, there are a few administrative issues to consider:

1. Your institution should assign one MIST-VR administrator who can configure the MIST-VR software (e.g. Frameset), and can troubleshoot any software or hardware complications.
2. Although this guide is designed for novice to intermediate MIST-VR users, your administrator should have a working knowledge of computer function, with the ability to navigate through a graphical user interface (e.g. Windows) without difficulty.
3. Ideally, your administrator should provide the bulk of the MIST-VR support to those experts helping to set performance levels, as well as oversee the training of residents randomized to curriculum based training.
4. The administrator will need the authority to ensure that testing and training is completed in a timely fashion. This is particularly important when dealing with experts whose schedules often compete with the completion of the MIST-VR tasks necessary to set expert performance levels.
5. In order to maintain anonymity, your experts will be identified using trial specific identifiers (e.g. Expert 1, Expert 2, Expert 3 etc . . .).

We hope that this guide will be helpful in your endeavors. Please do not hesitate to contact us with any questions you may have.

Section 1: Preliminary Startup

To conduct this trial successfully, it is important to recruit as many laparoscopic experts as possible. In this way, we will be able to ensure that the performance criterion levels that are set for the residents undergoing curriculum based training accurately reflect a relatively normal distribution of expertise seen throughout participating centers. As such, we expect a number of experts to participate from each center. Currently at Emory, seven experts have volunteered.

Officially, we are defining an “expert” as any individual that has performed 100 or more laparoscopic cholecystectomies. Once identified, an expert will perform 5 trials of the 6 MIST-VR Core Skills 1 tasks of AcquirePlace, TransferPlace, Traversal, WithdrawInsert, Diathermy, and Manipulation Diathermy using the specific task configurations set for the MASTER CBLC multicenter trial.

Each individual trial (of all 6 tasks) should be completed in its entirety during a given session. Experts may complete several complete trials in one session if they so choose. We recommend that they not complete all five trials in a single session, however. On average, each trial takes approximately forty-five minutes to complete. The unique CBLC task settings are purposefully difficult and will take longer to complete than when performed on the default easy, medium, or even hard, settings that your experts may be accustomed to.

If an expert is completely unfamiliar with the MIST-VR environment, a practice run on the medium MIST-VR task settings can be performed. In this case, a detailed explanation of the MIST-VR scoring matrix (especially the errors scored) should be undertaken prior to the first performance of each task, unless the expert is familiar with the MIST-VR environment. If you are unfamiliar with these particular metrics, please refer to the MIST-VR documentation provided with your simulator.

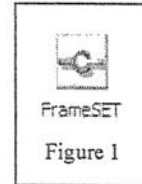
Each expert will have their own preference as to how they would like their environment set. Often darkened lighting, a quiet room, or adjustment of the instruments will be requested. To accommodate such requests, we have not set a standard testing environment. Unusual requests (e.g. sitting) will need to be discussed with the trial coordinators prior to acceptance, however.

Lastly, there are two points about the scoring metrics that should be discussed with experts prior to starting these tasks. First, we are primarily concerned with errors and instrument economy. In this respect, time to completion is weighed less heavily in our calculations. Within the MIST-VR, however, time is a significant factor affecting the final score. For this reason, final scores should not be provided as a gauge for expert performance progression. This is also why using the graphing function provided by FrameSET (e.g. peer-to-peer or progression) are not used during these expert trials. Second, during the last task (manipulation diathermy) it is okay to pull the sphere out of the large box (after initially grasping it) in order to position the diathermy box into a safer, more acceptable position. The MIST-VR environment will sometimes place the

diathermy box in an unsafe position (e.g. completely behind the sphere, or very close to the grasping instrument). In these cases we prefer to score safety over exceptional dexterity, and therefore have eliminated this particular error from the manipulation diathermy task. The precedent behind both of these adjustments was set during previous trials studying the effectiveness of the MIST-VR as a means to train safer surgeons.

Section 2: Configuring MASTER CBLC specific settings

Step 1: Load FrameSET by double clicking the Frameset icon shown In Figure 1. If you cannot find this icon readily, the Frameset program can be found in the windows folder: (c:/Program Files/FrameSET/).



Step 2: Login to the FrameSET administrator mode by using your administrative username and password. If you do not remember these codes, remember that Mentice occasionally sets the administrator default to username = a; password = a.

Step 3: Once inside the FrameSET administrator mode, left click on the plus sign to the left of the FrameSET menu choice in the left sided window pane (Figure 2). Several branches will present under the FrameSET data tree. In this section you will be concerned with the Tasks option.

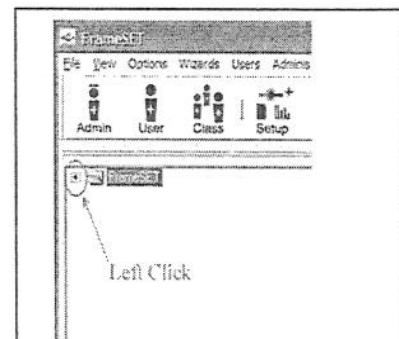


Figure 2

Step 4: Left click on the plus sign to the left of the Tasks folder as shown in Figure 3. The branches off the Tasks folder are all the MIST-VR tasks available on your computer. Within the MASTER CBLC trial, we are using the Core Skills 1 task set. This includes the following tasks: Acquire Place, Transfer Place, Traversal,

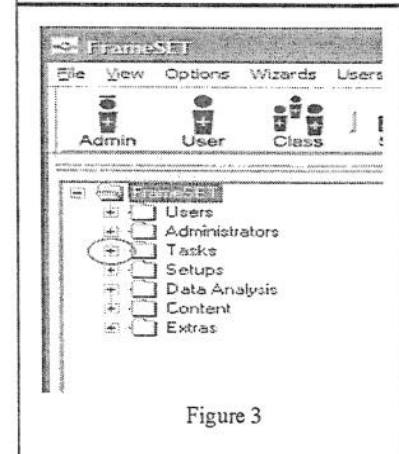


Figure 3

Withdraw/Insert, Diathermy, and Manipulation Diathermy. For now, you will set a new configuration for Acquire Place.

Step 5: Left click on the plus sign to the left of the Acquire Place choice (Figure 4).

This will branch into Configs and Weightings. Right click on the Configs text (not on the arrow), and choose Add Config from the pop-up menu item. In the right window pane, a new window will appear. Your screen should look like Figure 4.

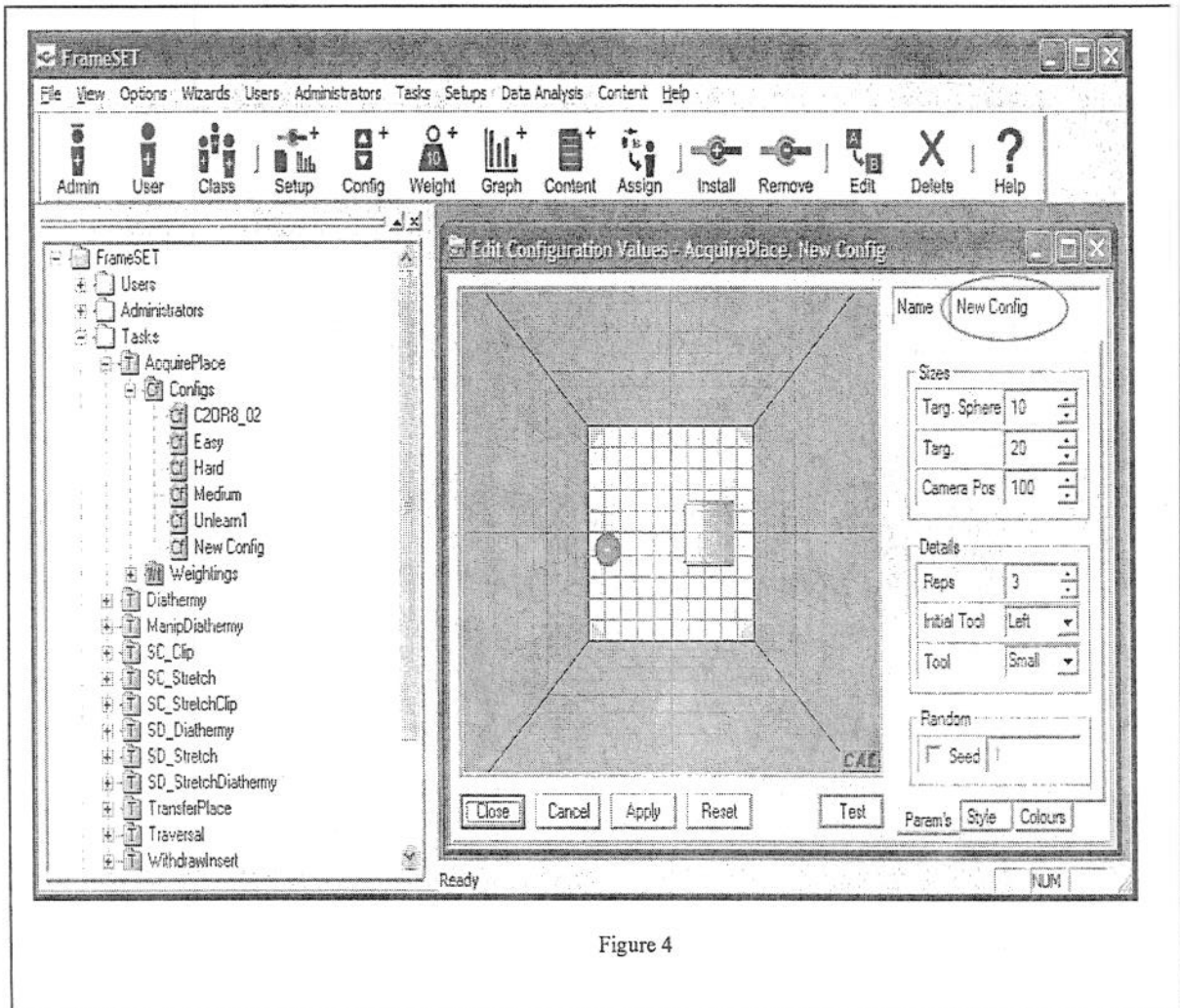


Figure 4

Step 6: Change the name of the New Configuration (circled in Figure 4), to MASTER CBLC. Once completed, click apply (circled in Figure 5).

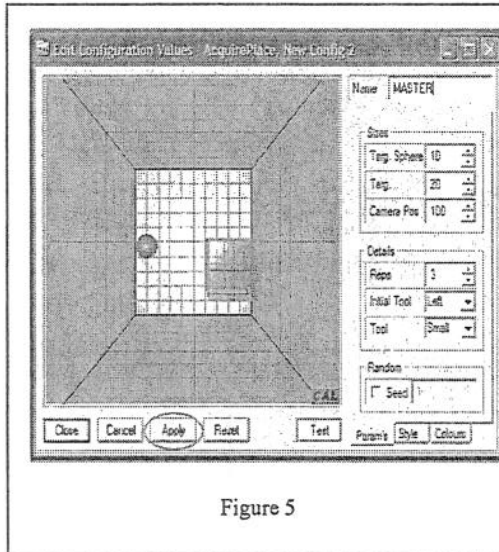


Figure 5

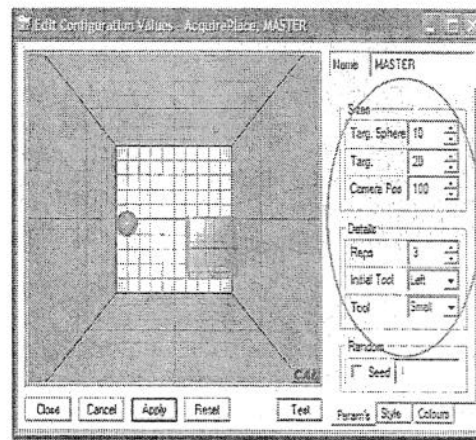


Figure 6

Step 7: Direct your attention to the circled area of

Figure 6 (above). Here is where the unique

MASTER CBLC configuration settings will be

applied. Change these settings to the following

specifications: Target Sphere = 7.5; Targ. = 9.25

(you will have to highlight the number and type it in

yourself. The arrows will not allow you to go below

10); Camera Pos = 100. Once complete, click on

apply, and check to make sure your settings match

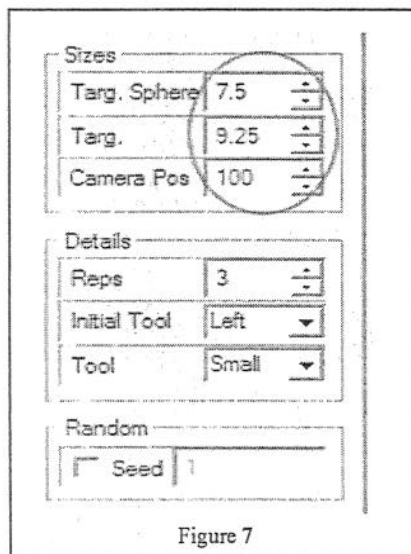


Figure 7

those in Figure 7. When complete, close the configuration window.

Step 8: The configuration for the Acquire Place task is now complete. Take similar steps to configure the remaining 5 tasks using the settings listed in Appendix 1. Be sure to close each configuration window when you are done changing the individual tasks – otherwise FrameSET will display an error window.

Section 3: Adding Classes and Users to MIST-VR

Step 1: Left click the plus sign to the left of the Users option within the FrameSET data tree (Figure 1). This will display the user classes (or groups) currently installed within your copy of FrameSET. In this section you will be creating your Expert class.

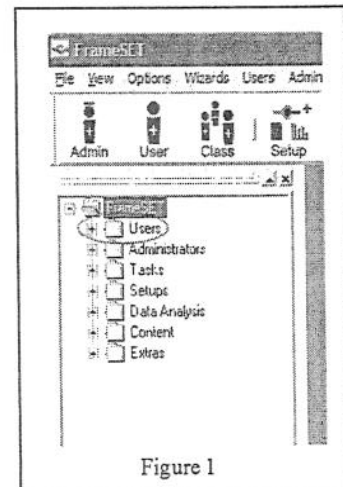


Figure 1

Step 2: The easiest way to create a class is to left click on the Class icon located on the FrameSET menu bar at the top of the main window (Figure 2). Next, type *MASTER CBLC Expert* for Class Name at the prompt (Figure 3).

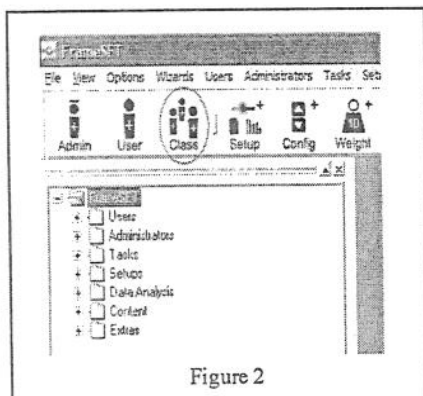


Figure 2

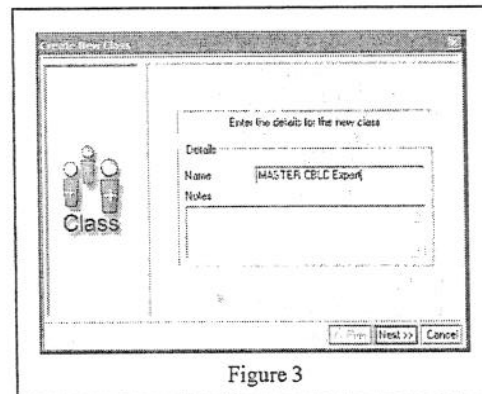


Figure 3

When you are finished typing, left click on the next button at the bottom of the window. The window will then ask whether you want to add users to this class. We have found that adding users in this fashion will crash the program; therefore you do not want to create users at this time. Continue on by clicking the Next button again. Your class should appear under the Users data tree in the window to the left.

Step 3: To add users, you can either a) left click on the Users icon on the FrameSET menu bar (Figure 4); or b) right click on the MASTER Expert Class item found in the data tree to the left.

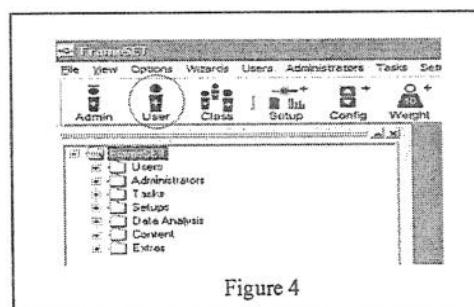


Figure 4

a) If you use the Users icon, use the subject's number as the account name, and be sure

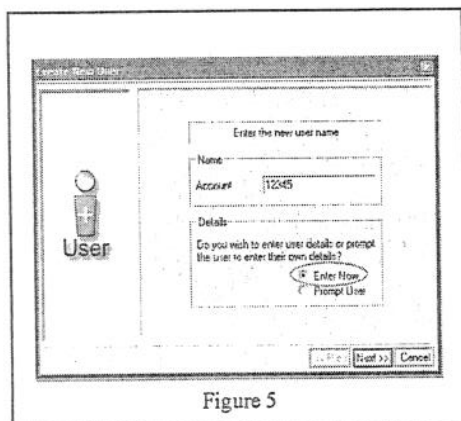


Figure 5

to left click on the Enter Now radial button in order to add more details (Figure 5). Left click the Next button on the bottom of the window to continue. Within the details section, use the expert's number as his/her last name (e.g. Expert 1). Next, choose a password that you can remember. Confirm the password and click the

Next button. The next window will ask you to select a user class for this new user. For this example you will choose the MASTER Expert class.

b) If you right click on the MASTER Expert Class in the data tree, add the subject's number as the account name and user first name. Next, choose a password you will remember (Figure 6). Click apply when you are finished.

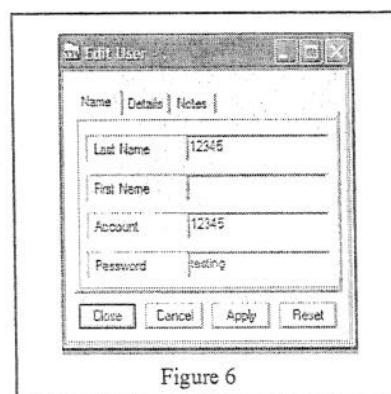


Figure 6

Section 4: Creating a MIST-VR task setup with assignments

Once you have designed a class and placed experts into it, you will need to add a task setup to the group. The task setup is the sequence of MIST-VR tasks that each user will be asked to perform. Since you are using the same task configuration settings that will be used when residents are training, you can use the same setup for both expert and training classes (once that class is made later in the trial). Here you create the MASTER Training setup that will be used for both of these groups – although it is specifically used for the experts in this initial portion of the trial.

Step 1: Left click on the Setup icon located on the FrameSET menu bar at the top of the

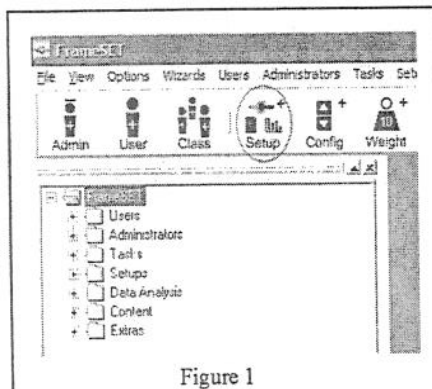


Figure 1

main window (Figure 1). Type *MASTER Training* in the setup name box. Move on to the next step by left clicking on the finish button.

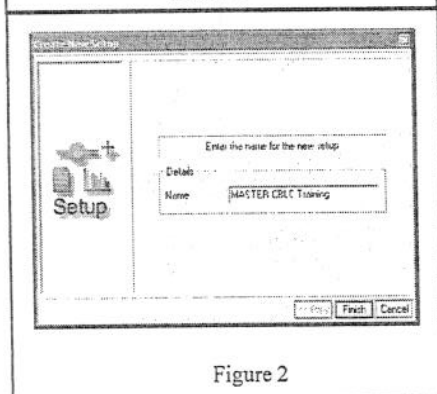


Figure 2

Step 2: You will need to add content, as introductory segments to the various skill tasks, as well as the tasks themselves. Add the introduction to the acquire place MIST-VR task by left clicking on the add button under the components portion of the window (Figure 3). When the pop-up menu appears, left click on the Content option.

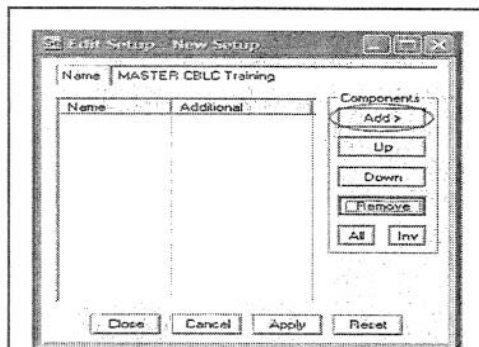


Figure 3

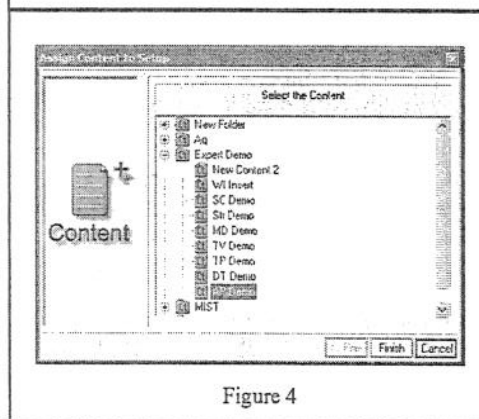


Figure 4

Next, left click the arrow to the left of the Expert Demo option. Choose the AP Demo option and check to make sure it was added to your setup listing (Figure 4).

Step 3: Now add the Acquire Place task. Left click on the add button under the components portion of the window. When the pop-up appears, choose the Task option. Choose AcquirePlace and then left click the Next button. A new window displaying the various task configuration options now appears.

Choose the Medium configuration and left click on the Finish button.

Step 4: Continue adding content and MASTER CBLC configuration tasks in the following order:
 Content → TP demo; Task → TransferPlace;
 Content → TV demo; Task → Traversal; Content → WI Insert; Task → WithdrawInsert; Content → DT demo; Task → Diathermy; Content → MD demo; Task → Manipulation Diathermy. When

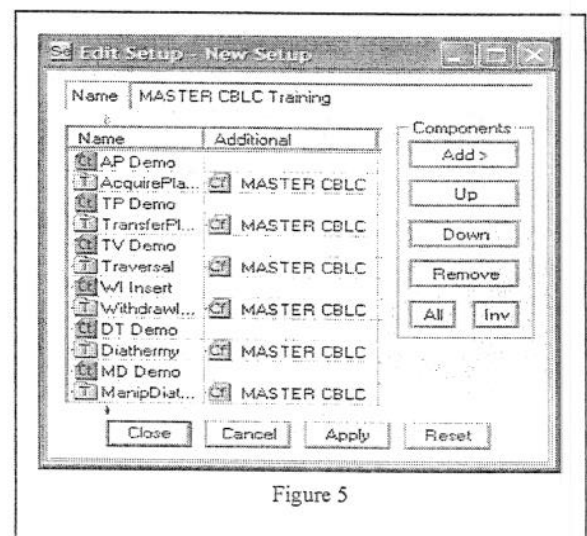


Figure 5

you are finished your window should look like Figure 5.

Step 5: Each expert will need to be assigned a task setup before using the MIST-VR system. Assignment is accomplished by left clicking on a setup and dragging the setup to a given user name. If the users of a given class are going to perform the same tasks, you can save time by dragging the setup over the class name instead of each individual user (Figure 6). For the MASTER lap. chole. trial the Training setup will be applied to the MASTER Expert class.

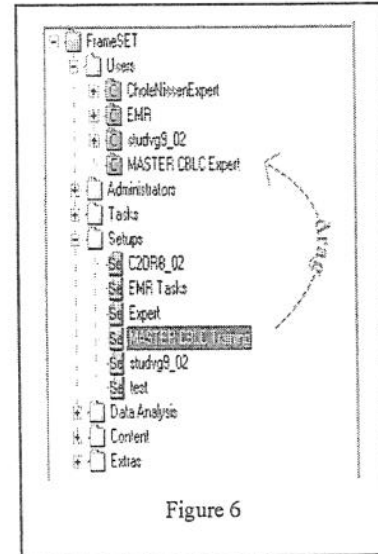
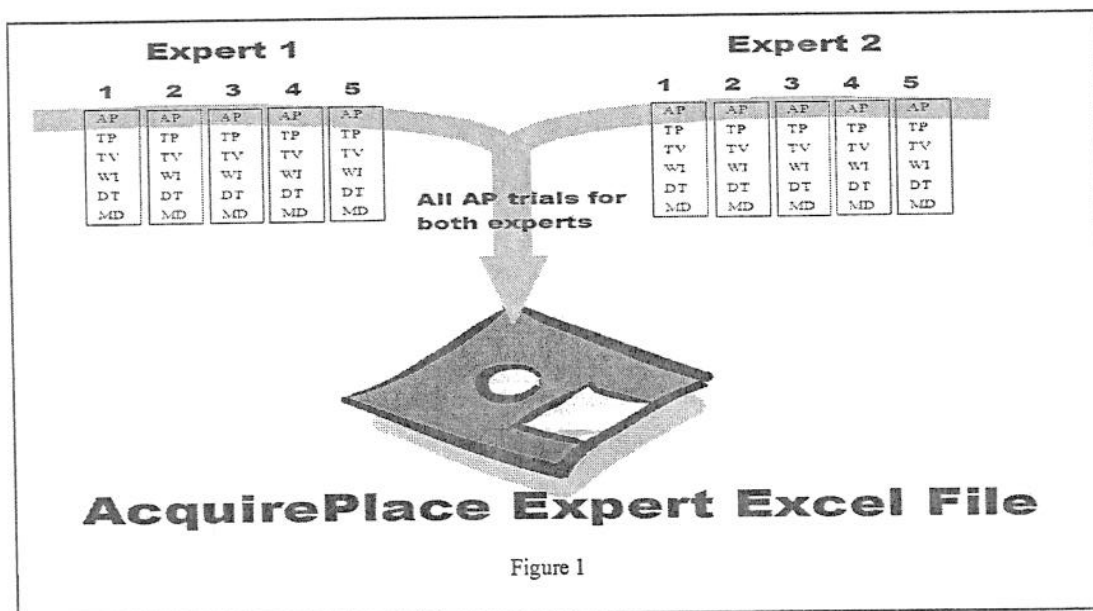


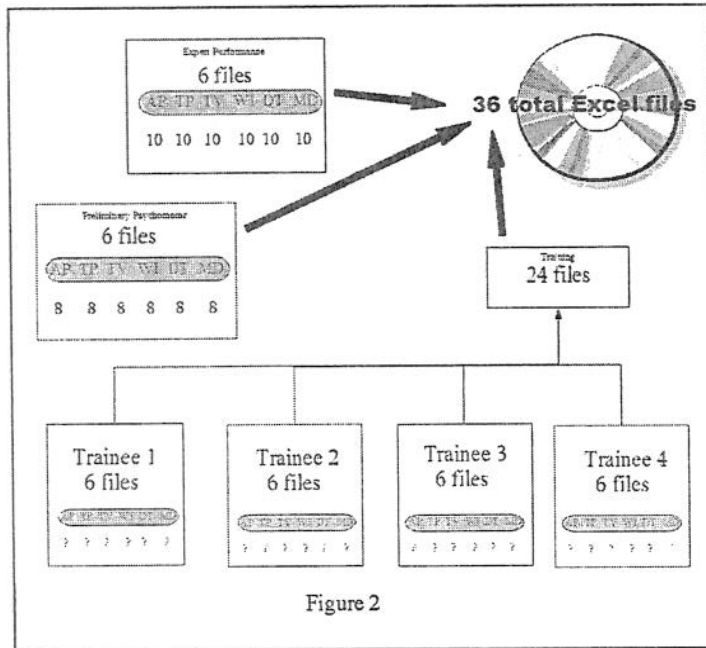
Figure 6

Section 5: Exporting MIST-VR/FrameSET data to Excel

Three sets of data will be needed for completion of this MASTER trial: the expert performance levels for each task, the results of the preliminary psychomotor testing of the individual subjects, and the performance of each subject during training. We have chosen to accept MIST-VR data for analysis in the Excel spreadsheet format. Unfortunately, there is no easy way to export all MIST-VR data from a specific user class into the same Excel spreadsheet. Instead, FrameSET only allows task specific data to exist on the same spreadsheet. For example, let's assume you have two experts at your institution who have completed their 5 MIST-VR trials to help set the expert criterion for the study. In order to have their data processed for statistical analysis, you will save six different Excel files – one for each individual MIST-VR task. In the case of the AcquirePlace task, this is conceptually depicted in Figure 1.



In the same example, if you enroll eight subjects with four of them randomizing to VR

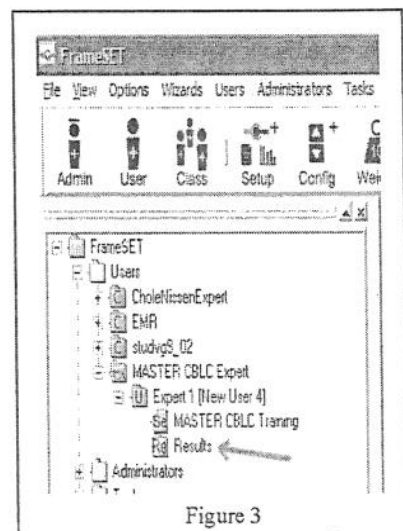


training, you will eventually send a total of 36 Excel files to Emory. This is shown in Figure 2. Also note that this figure has the number of rows each Excel file should contain (e.g. 2 experts, 5 trials = 10 rows). There are question marks underneath the tasks performed by the trainees due to our inability

to predict how many training trials it will take to reach performance criterion levels.

Now, with an understanding of what you will be sending, what follows is a description of the export and saving process using the psychomotor testing data as an example. Like previous examples, mimicking these steps will allow you to save and package the remaining data when needed. If you do not have Excel installed on the computers running FrameSET, there is an alternative work-around that is described in Appendix 3.

Step 1: Navigate through the Frameset data tree (left clicking the plus signs to the left of the text items) to find the users in the MASTER Expert class. Left click the plus sign



on each of the users until you see a Results item under each user (Figure 3).

Step 2: Left click on the plus sign next to the Results item under the first user listed (a plus sign will appear after the expert has completed a trial). The MIST-VR Core Skills 1 tasks are then listed beneath. Left-click the plus sign next to the AcquirePlace task.

Step 3: Underneath you will find a Cf (or configurations) folder named Medium. Within this folder are the raw scores of the user's one trial of AcquirePlace during the initial psychomotor testing. Left click on the plus sign to see the Re (or Results) folder named with the date and time the task was performed.

Step 4: Right click on the results folder and choose the Display option from the pop-up menu. You should see a window labeled "Display Results – AcquirePlace, Medium Configuration" in the right sided window pane (Figure 4).

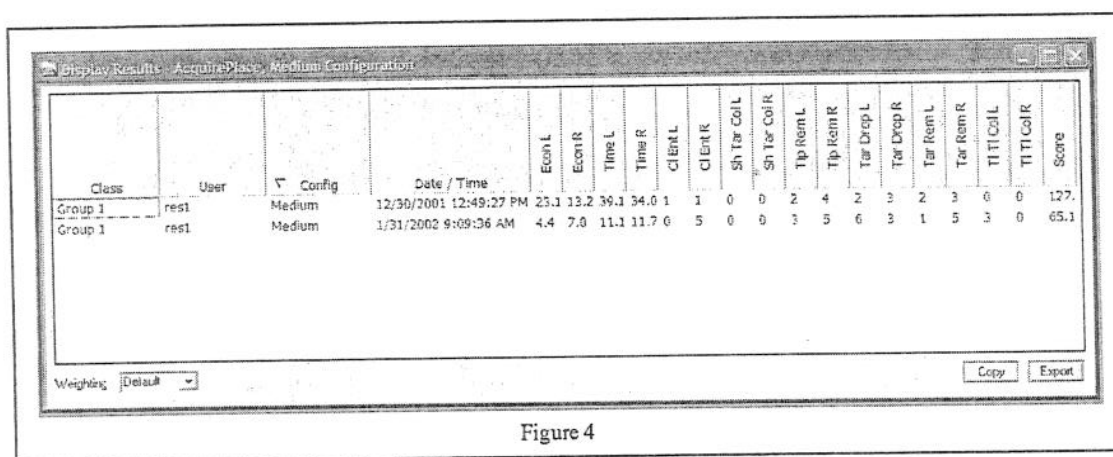


Figure 4

Step 5: You will now need to add the remainder of the experts' AcquirePlace results in the display results window by repeating Steps 2-4 for each user.

Step 6: Export the data to an Excel spreadsheet by left clicking on the Export button on the bottom of the display results window (Figure 5). The program will then ask for a file name. As listed in Appendix 2, the file name for this file (collected at Emory) should be *MastLCEmoryExpertAP*. Choose a folder to save the Excel file in, and left click on the Save button at the bottom of the window.

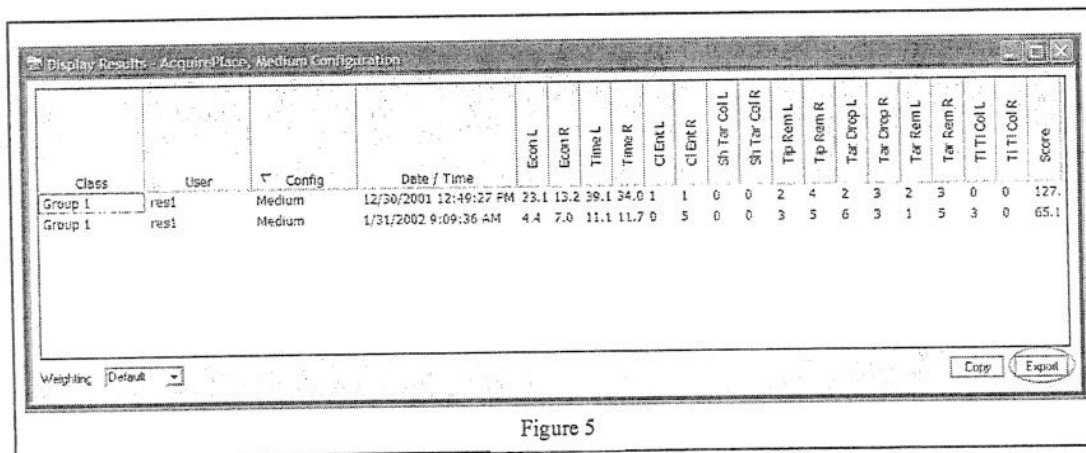


Figure 5

Step 7: Repeat Steps 2-6 for each respective MIST-VR task. Use the naming conventions listed in Appendix 2.

Step 8: Place all Excel files on a CD-Rom, or 3.5" floppy disk and send them to the Emory Endosurgery Center as listed on the title page.

Appendix 1: MIST-VR CBLC configurations

	Target Sphere	Target Box	Diathermy Box	Length	Radius	Number	Camera Position
Acquire Place	7.5	9.25	-----	-----	-----	-----	100
Transfer Place	7.5	9.25	-----	-----	-----	-----	100
Traversal	-----	-----	-----	5	2.5	6	100
Withdraw/Insert	7	9	-----	-----	-----	-----	100
Diathermy	4	-----	3.5	-----	-----	-----	100
Manipulation Diathermy	7.5	17.5	6.5	-----	-----	-----	100

Appendix 2: File naming

File naming template: MastLC *X Y Z*.xls

MastLC stands for MASTER Laparoscopic Cholecystectomy

X = Institution name

Y = Study component

Z = MIST-VR task

Institution name abbreviations
Use the first five letters of your institution name. Alternatively, you can choose an abbreviation ≤ 5 characters that may be more fitting as an identifier (e.g. UNC).

Study component abbreviations	
Setting expert criterion	Expert
Psychomotor testing	Psych
Training	Train

MIST-VR task abbreviations	
AcquirePlace	AP
TransferPlace	TP
Traversal	TV
WithdrawInsert	WI
Diathermy	DT
Manipulation Diathermy	MD

Example: For a group of Emory University experts who have finished their 5 MIST-VR trials, the name for the Manipulation Diathermy task results file should be:

MastLCEmoryExpertMD

Appendix 3: Exporting data without using Excel

This appendix is intended for institutions that are unable to use Excel as their means of data presentation and packaging for analysis. To see how to manipulate FrameSET in order to export user data for the MASTER Laparoscopic Cholecystectomy trial, please refer to Section 4 in this instruction guide.

To export your data you will need to have a text editor loaded on the computer the data is being exported from. Examples include the Microsoft programs NotePad, or WordPad that are provided with the Microsoft operating system software. Most likely, one of these programs is already loaded on your computer, and can be found within the Accessories folder located within the programs region of the Start menu.

In Section 4 of the instruction guide, Step 6 asks you to click on an export button that automatically saves data in an Excel format. Instead of performing this task, you will need to cut and paste all of the user data from the results window into your text editor.

Step 1: Using your mouse, highlight all the users and their results.

Step 2: Making sure that all the data remains highlighted, click on the Copy button on the lower portion of the window. This will place all the highlighted data in the windows clipboard so that you can paste it into your text editing program.

Step 3: Paste the data into your text editing program using the appropriate commands for the program. In NotePad or WordPad, you can find the paste command under the Edit menu item on the top toolbar.

Step 4: Save the data using the appropriate file name as discussed in Appendix 2. Files saved using this method will have a .txt extension instead of the .xls extension discussed above.